

*Toms v. Brown University et al.*

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

DR. STEVEN TOMS,	:	
Plaintiff	:	
	:	
v.	:	C.A. No. 2024-_____
	:	
BROWN UNIVERSITY,	:	<b>JURY TRIAL DEMANDED</b>
	:	
LIFESPAN CORPORATION	:	
d/b/a BROWN UNIVERSITY	:	
HEALTH	:	
	:	
RHODE ISLAND HOSPITAL	:	
d/b/a BROWN UNIVERSITY	:	
HEALTH CANCER	:	
INSTITUTE	:	
	:	
Defendants.	:	

**COMPLAINT FOR CORRECTION OF INVENTORSHIP REGARDING JOINT  
INVENTORSHIP IN A PENDING PATENT APPLICATION**

Plaintiff, Dr. Steven Toms (hereinafter “Plaintiff”), brings this action under the Patents Law, 35 U.S.C. § 116 for non-joinder of a joint inventor in a pending patent application against Brown University, Lifespan Corporation d/b/a Brown University Health, and Rhode Island Hospital d/b/a Brown University Health Cancer Institute (hereinafter collectively referred to as “Defendants”) seeking correction of the pending patent application, invalidation of claims at issue pertaining to the joint inventorship under this complaint, or invalidation of the entire patent at issue under this complaint.

**NATURE OF THIS ACTION**

1. Plaintiff seeks the correction of inventorship of the United State Patent Application titled **NITROPHENYL-ACRYLAMIDES AND USES THEREOF** with an

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Application Number 18/555,505 (hereinafter “the ‘505 application”), a National Stage Entry of PCT Application No. PCT/US22/25068 filed April 15, 2022 (hereinafter “the ‘068 application”), claiming priority to the Provisional Patent Appl. No. 63/175,476 with a filing date of April 15, 2021 (hereinafter “the ‘476 application”).

**PARTIES, JURISDICTION, AND VENUE**

2. Plaintiff is an individual with a with a domicile in Massachusetts.

3. Upon information and belief, Defendant Brown University, is a domestic non-profit corporation incorporated in Rhode Island and with its principal place of business at 1 Prospect St, Providence, RI 02903.

4. Upon information and belief, Defendant Lifespan Corporation d/b/a Brown University Health as of August 15, 2024, is a domestic non-profit corporation incorporated in Rhode Island and with its principal place of business at 167 Point St, Providence, RI 02903.

5. Upon information and belief, Defendant Rhode Island Hospital d/b/a Brown University Health Cancer Institute as of August 15, 2024, is a domestic non-profit corporation incorporated in Rhode Island and with its principal place of business at 593 Eddy St, Providence, RI 02903.

6. This Complaint alleges a cause of action under the Patent Law 35 U.S.C. § 116 seeking correction of inventorship of the ‘505 application.

7. This Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331, 1332, and 1338(a).

8. This Court has personal jurisdiction over Defendants pursuant to Defendants’ incorporations and principal places of business being located in Rhode Island.

9. Venue is appropriate over the parties to this Complaint pursuant to 28 U.S.C. §§ 1391(b) and 1391(c).

**FACTUAL BACKGROUND**

10. Plaintiff worked for Defendants from 2016 to 2023.

11. Plaintiff, principal investigator, and Dr. Tapinos (hereinafter “First Named Inventor”), co-principal investigator, were co-investigators for Warren Alpert Foundation Grants.

12. Plaintiff and First Named Inventor jointly shared laboratory space, equipment, and students.

13. On April 15, 2021, Defendants applied as Applicant for a provisional patent, the ‘476 application, entitled **NITROPHENYL-ACRYLAMIDES AND USES THEREOF**.

14. On April 15, 2022, Defendants applied as Applicant for an international patent, the ‘068 application, claiming priority to the ‘476 application, entitled **NITROPHENYL-ACRYLAMIDES AND USES THEREOF**.

15. On October 13, 2023, Defendants applied as Applicant for the ‘505 application, entitled **NITROPHENYL-ACRYLAMIDES AND USES THEREOF**, a National Stage Entry of the ‘068 application, claiming priority to the ‘476 application.

16. Nitrophenyl-acrylamides may be useful for treating a disease, such as a brain tumor, including glioblastoma.

17. Defendants applied for the ‘505 application and named only three inventors: NIKOLAOS TAPINOS (First Named Inventor), DAVID KARAMBIZI, and JOHN ZEPECKI.

18. All three inventors assigned all rights in the ‘505 application to Defendants.

19. Defendants did not name Plaintiff as a joint inventor on the ‘505 application.

20. Claim 15 of the ‘505 application, currently amended, claims “[A] method of treating cancer in a subject in need thereof, comprising administering a therapeutically effective amount of entacapone or a pharmaceutically acceptable salt thereof or the compound of claim 1 to the subject.”

21. Claim 1 claims a compound of nitrophenyl acrylamide by formula or an acceptable salt thereof.

22. Claim 18 of the ‘505 application claims “[T]he method of claim 15, wherein the cancer comprises a brain cancer or tumor, a leukemia, a breast cancer, a lung cancer, a colon cancer, a pancreatic cancer, an ovarian cancer, a prostate cancer, or a kidney cancer.”

23. Claim 19 of the ‘505 application, currently amended, claims “[A] method of inhibiting the fat mass obesity-associated protein (FTO) or Notch1 activity in a cell, comprising contacting the cell with an effective amount of entacapone or a pharmaceutically acceptable salt thereof, the compound of claim 1.”

24. Claim 20 of the ‘505 application, currently amended, claims “[T]he method of claim 19, wherein: the cell is a brain cell, a blood cell, a breast cell, a lung cell, a colon cell, a pancreatic cell, an ovarian cell, a prostate cell, or a kidney cell, and optionally the contacting is in a subject; or the contacting is in vitro, and optionally the cell is a brain cell, a blood cell, a breast cell, a lung cell, a colon cell, a pancreatic cell, an ovarian cell, a prostate cell, or a kidney cell.”

25. Claim 21 of the ‘505 application, currently amended, claims “[T]he method of claim 19, wherein the cell is a glioma stem cell.”

26. The ‘505 application is attached as Exhibit 1.

27. Under the Executive Summary, Plaintiff and First Named Inventor worked as team members.

28. Under the Executive Summary, Plaintiff and First Named Inventor reported progress on understanding the novel role of miRNA, including regulating m6A RNA demethylation, thereby affecting nascent protein translation.

29. Plaintiff and First Named Inventor were co-authors of a PLOS Genetics research article titled “miRNA-mediated loss of m6A increases nascent translation in glioblastoma.”

30. Plaintiff was listed as a co-investigator on a submission for “The role of m6a RNA methylation and inhibition in human glioblastoma.”

31. Under the Executive Summary, Plaintiff and First Named Inventor positively identified miRNA interaction with RRACH.

32. Under the Executive Summary, Plaintiff and First Named Inventor began to further investigate the role of FTO inhibition in glioblastoma multiforme (GBM).

33. Plaintiff was listed as co-investigator on the 2020 Cancer Center at Brown University pilot project award for “Identification of the FTO inhibitor entacapone as therapeutic agent for human glioblastoma.”

34. Plaintiff is a co-author of a World Neurosurgery research article titled “The Role of Circulating MicroRNA in Glioblastoma Liquid Biopsy.”

35. Under the Executive Summary, entacapone had been found to be potent in inhibiting cell proliferation in GBM.

36. Under the Executive Summary, a primary effector of this appeared to be the impact of m6A demethylation of the mRNA of the gene Notch1.

37. Given the role Notch1 played in other cancers, Plaintiff and First Named Inventor then ordered and tested entacapone on a triple negative breast cancer line and saw marked inhibition of cell proliferation.

38. Under the Executive Summary, Plaintiff was completing a Nanostring analysis to look at the gene expression patterns in lung and breast cancer human tissue samples.

39. The Executive Summary is attached as Exhibit 2.

40. On September 3, 2022, First Named Inventor stated that Plaintiff's work on the miRNA liquid biopsy project and Nanostring analysis on lung and breast cancer should be Plaintiff's and distinct from First Named Inventor.

41. The email is attached as Exhibit 3.

### **CLAIM FOR RELIEF**

#### **CORRECTION OF INVENTORSHIP IN ACCORDANCE WITH 35 U.S.C. § 116**

42. Plaintiff repeats and realleges paragraphs 1 through 41 hereof, as if fully set forth herein.

43. Defendants failed to properly identify all inventors when Defendants filed for the '505 application in accordance with 35 U.S.C. § 116.

44. Plaintiff is a joint inventor under 35 U.S.C. § 116 because Plaintiff contributed to the conception of at least one claim in the '505 application.

45. In fact, Plaintiff contributed to multiple claims through joint behavior, collaboration, and working under common direction.

46. Plaintiff contributed to Claim 15 of the '505 application for a method of treating cancer in a subject in need thereof, comprising administering a therapeutically effective amount of entacapone.

47. Plaintiff knew that entacapone had been potent in inhibiting cell proliferation. Plaintiff and First Named Inventor decided to test entacapone on triple negative breast cancer and saw marked inhibition of cell proliferation.

48. Plaintiff contributed to Claim 18 of the '505 application for the method of Claim 15, wherein the cancer comprises a brain cancer or tumor, a leukemia, a breast cancer, a lung cancer, a colon cancer, a pancreatic cancer, an ovarian cancer, a prostate cancer, or a kidney cancer.

49. Specifically, Plaintiff contributed to the method of Claim 15 wherein the cancer comprises breast cancer and lung cancer because Plaintiff's work on lung and breast cancer in relation to this application were Plaintiff's alone, separate and distinct from First Named Inventor.

50. Plaintiff contributed to Claim 19 of the '505 application for a method of inhibiting fat mass obesity-associated protein (FTO) or Notch1 activity in a cell, comprising contacting the cell with an effective amount of entacapone or pharmaceutically acceptable salt thereof or the compound of claim 1.

51. Plaintiff contributed to Claim 19 of the '505 application because Plaintiff and First Named Inventor together investigated the role of FTO inhibition in GBM. Plaintiff knew that entacapone had been potent in inhibiting cell proliferation in GBM. The primary effector of this appeared to be the impact of m6A demethylation of the mRNA of the gene Notch1, a research article of which Plaintiff and First Named Inventor were co-authors. Plaintiff and First Named Inventor then ordered and tested entacapone on a triple negative breast cancer line and saw marked inhibition of cell proliferation.

52. Plaintiff contributed to Claim 20 of the ‘505 application for the method of claim 19, wherein the cell is a breast cell or a lung cell.

53. Specifically, Plaintiff contributed to the lung and breast cancer, and in which First Named Inventor stated that this was Plaintiff’s own work, separate and distinct from First Named Inventor’s work.

54. Plaintiff contributed to Claim 21 of the ‘505 application for the method of claim 19, wherein the cell is a glioma stem cell.

55. Specifically, Plaintiff contributed to the method of inhibiting FTO or Notch1 activity in a cell, wherein the cell is a glioma stem cell, because Plaintiff and First Named Inventor together investigate the role of FTO inhibition in GBM. As Plaintiff contributed to claim 19, Plaintiff therefore contributed to claim 21, a method of claim 19.

56. Therefore, Plaintiff is a joint inventor to at least claims 15, 18, 19, and 20 of the ‘505 application.

**RELIEF REQUESTED**

WHEREFORE, Plaintiff requests judgment against the Defendants as follows:

1. Defendants have violated 35 U.S.C. § 116 in failing to name all inventors to the ‘068 application.

2. Enjoin Defendants to correct the ‘505 application by amending inventorship of the ‘068 application to include Plaintiff as an inventor.

3. Invalidate Claims 15, 18, 19, and 20 based on the failure of Defendants to properly name all inventors to the ‘505 application.



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4. Preliminary and permanent injunction enjoining Defendants from asserting rights and exclusivity to claims 15, 18, 19, 20, and 21 of the ‘505 application due to failure to name all inventors.

5. Invalidate the patent based on Defendants’ violation of 35 U.S.C. § 116 in failing to name all inventors to the ‘505 application.

6. Preliminary and permanent injunction enjoining Defendants from asserting rights and exclusivity to the entire ‘505 application due to failure to name all inventors.

**JURY TRIAL DEMANDED ON ALL ACCOUNTS THAT MAY BE SO TRIED.**

Dr. Steven Toms

By his attorney,

/s/ alan f feeney

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